K122890

510(k) SUMMARY
Inion CPS® Orbital Plate

JAN 29 2013

Manufacturer and submitter:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date:	December 20, 2012
Contact person	Kati Marttinen, Quality and Regulatory Director Phone: +358 10 830 6600 Fax: +358 10 830 6691 kati.marttinen@inion.com
Establishment registration number	9710629
Trade name of the device	Inion CPS® Orbital Plate
Device classification and product code	Class II (Special controls) Classification Panel: Dental Product Code: JEY Common name: Bone plate Regulation number: 872.4760
Predicate device	Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System K010352
Conformance with performance standards	No applicable mandatory performance standards exist for this device. Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

Inion CPS® Orbital Plates are intended for use in trauma and reconstructive procedures of the orbital cavity as part of the Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System.

The Inion CPS® Orbital Plate fixation plates made of resorbable polylactic acid/trimethylcarbonate copolymer: This copolymer degrades *in vivo* by hydrolysis into L-lactic, D-lactic and TMC monomers which are then metabolised by the body.

Inion CPS® Orbital Plates are of dimensions: length: 25-40 mm, width: 24-40 mm, thickness: 0.5 mm. The fixation of the plates will be done with Inion CPS® ø1.5 mm screws. The implants retain sufficient strength to fulfil their intended function during the healing period of the fracture or osteotomy, and degrade gradually thereafter. Bioresorption takes place within two to four years. The implants are provided sterile to the user and are not to be resterilized.

The Inion CPS® Orbital Plates provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.

The Inion CPS® Orbital Plates are designed to be used with customized instrumentation consisting of template, drill bits, bone taps, screw driver, plate benders and a heating device.

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INION

Indications for use

Inion CPS Orbital Plates are intended for use in trauma and reconstructive procedures of the orbital cavity as part of the Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System.

Performance testing for substantial equivalence determination

Mechanical shear test and biomechanical fixation test were performed to verify the strength and fixation properties of Inion CPS Orbital Plates and to compare them to the predicate devices. Testing was conducted initially and during in vitro degradation.

In vitro degradation testing was carried out to determine the degradation profile (i.e., change in material and mechanical properties) and verify the sufficiency of the mechanical stability over healing period as the polymer degrades during *in vitro* degradation and to ensure the degradation of the Inion CPS Orbital Plates.

Functional and handling test and simulated clinical use test were performed to verify that the implants, accessory instruments, packaging and instructions for use are functioning together as intended, and conform to the defined user needs and intended uses.

The data demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion CPS Orbital Plates are substantially equivalent with the predicate device Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System (K010352). The devices have passed the tests for functionality and handling in simulated clinical use settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 29, 2013

Ms. Kati Marttinen
Quality and Regulatory Director
Inion Oy
Lääkärinkatu 2
Tampere, Finland 33520

Re: K122890
Trade/Device Name: Inion CPS® Orbital Plate
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 3, 2013
Received: January 18, 2013

Dear Ms. Marttinen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122890

Statement of Indications for Use

510(k) Number: K122890

Device Name: Inion CPS® Orbital Plate

The **INION CPS Orbital Plates** are intended for use in trauma and reconstructive procedures of the orbital cavity as part of the Inion CPS 1.5/2.0/2.5 Bioabsorbable Fixation System.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA 2013.01.23 12:38:45 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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